



#14  
m.m.  
8/12/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of )  
LABERGERIE ERIK ET AL. )  
Serial No.09/819,496 ) Art Unit: 1615  
Filed: March 28, 2001 ) Examiner: R.M. JOYNES

FOR: PULVERULENT MANNITOL AND PROCESS FOR PREPARING IT

DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks  
Washington, D.C.

Sir:

I, Philippe LEFEVRE, of 54, route de Merville,  
59400 MERVILLE, France, do solemnly declare:

THAT I am a graduate of "Ecole Nationale Supérieure  
de Chimie" - 59000 LILLE - FRANCE

THAT I have been working as chemical engineer since  
the 28<sup>th</sup> of January, 1985 and that I now hold the  
position of manager of the Pharmaceutical and Cosmetic  
Applications Department by ROQUETTE FRERES;

THAT I am a named inventor on the present patent  
application n° 09/819,496, I am fully familiar therewith  
and I am competent to give an opinion regarding the  
techniques and subject matter thereof;

THAT the operating instructions entitled "POWDER  
CHARACTERISTICS TESTER OPERATING INSTRUCTIONS" from  
HOSOKAWA IRON WORKS, LTD. OSAKA, JAPAN and provided with  
the letter dated November 11, 2001, came to my knowledge  
before the filing of the present application;

THAT I used said operating instructions for  
measuring the packed bulk density of the pulverulent  
mannitol of the present application;

THAT, said operating instructions were also widely used by the person skilled in the art using the HOSOKAWA apparatuses before and at the time of the filing of the present application;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 24/06/02

LEFEVRE Philippe

A handwritten signature in black ink, appearing to be 'C. Lefevre', with a stylized, sweeping flourish at the bottom.



## ANNEX I

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

JUL 29 2002

TECH CENTER 1600/2900

In re application of )  
LABERGERIE ERIK ET AL. )  
Serial No.09/819,496 ) Art Unit: 1615  
Filed: March 28, 2001 ) Examiner: R.M. JOYNES

FOR: PULVERULENT MANNITOL AND PROCESS FOR PREPARING IT

### DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks  
Washington, D.C.

Sir:

I, Philippe LEFEVRE, of 54, route de Merville,  
59400 MERVILLE, France, do solemnly declare:.

THAT I am a graduate of "Ecole Nationale de chimie"  
- 59000 LILLE - France;

THAT I have been working as chemical engineer since  
the 28th of January 1985, and that I now hold the  
position of manager of the Pharmaceutical and Cosmetic  
Applications Department by ROQUETTE FRERES;

THAT I am well acquainted in the chemistry of  
sugars and in particular in the field of pulverulent  
mannitol ;

THAT I am a named inventor on the present patent  
application n° 09/819,496, I am fully familiar therewith  
and I am competent to give an opinion regarding the  
techniques and subject matter thereof;

THAT I have read and understood the Office Action  
mailed on March 18, 2002 in connection with the present  
patent application;

THAT I have also read and understood US Patent  
n° 5,573,777 to Serpelloni et al., in particular the  
examples of said patent;

THAT I routinely perform measurements of packed bulk density on pulverulent mannitols;

THAT I performed the tests joined in annex which clearly show that the pulverulent mannitol of the invention differs in its structure and properties from the pulverulent mannitol of Serpelloni et al. and that this difference allows new applications such as the filling of hard capsules in the pharmaceutical field;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

16/07/02

LEFEVRE Philippe



In re application of LABERGERIE ET AL - Serial No. 09/819,496  
 July 18, 2002

## ANNEX II

**TABLE COMPARING THE CHARACTERISTICS OF THE  
 PULVERULENT MANNITOL OF THE INVENTION WITH THE  
 MANNITOL OF SERPELLONI ET AL.**

	<b>PULVERULENT MANNITOL OF THE INVENTION</b>		<b>PULVERULENT MANNITOL OF SERPELLONI ET AL</b>	
	Lab 2695 Sample X0201	Lab 2695 Sample X0104	PEARLITOL 200 SD Sample E455M	PEARLITOL 100 SD Sample E272 M
Packed bulk density	<u>0.72</u>	<u>0.71</u>	0.54	0.58
Flow factor HOSOKAWA	76	65	81	79
Rate of dissolution in water of the fraction 100 – 200 µm	20 s	20 s	< 10 s	< 10 s
Rate of dissolution in water	40 s	40 s	< 10 s	< 10 s
Average diameter (Laser particle size analysis)	178 µm	126 µm	174 µm	101 µm



In re application of LABERGERIE ET AL - Serial No. 09/819,496  
July 18, 2002

RECEIVED  
JUL 29 2002  
TECH CENTER 1600/2900

### ANNEX III

#### ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF THE INVENTION - REF LAB 2695 - SAMPLE X0104

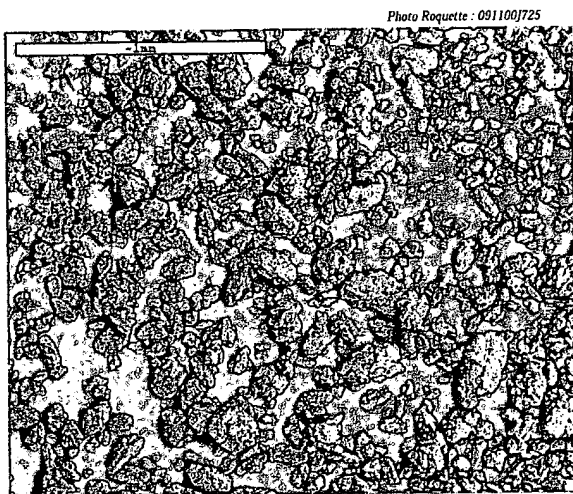


Photo 1: Lab 2695 sample X0104  
Magnification: 38.5 X



Photo 2: Lab 2695 sample X0104  
Magnification: 154 X

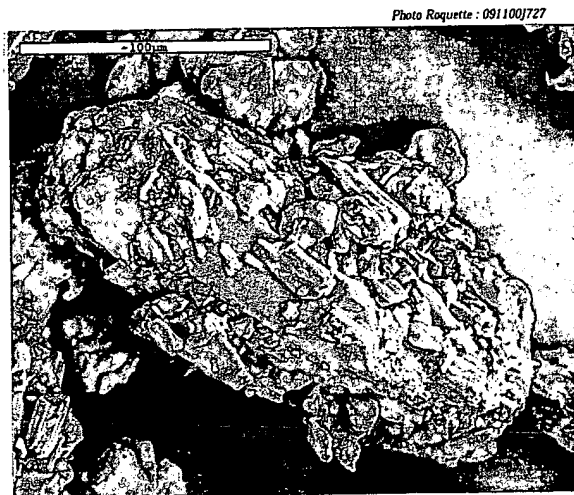


Photo 3: Lab 2695 sample X0104  
Magnification: 385 X



In re application of LABERGERIE ET AL - Serial No. 09/819,496  
July 18, 2002

RECEIVED  
JUL 29 2002  
TECH CENTER 1600/2900

## ANNEX IV

### ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF THE INVENTION - REF LAB 2695 - SAMPLE X201

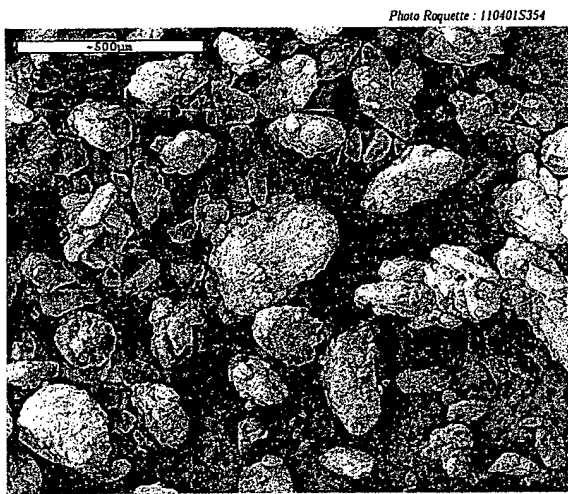


Photo 1: Lab 2695 sample X201  
Magnification: 57.5 X

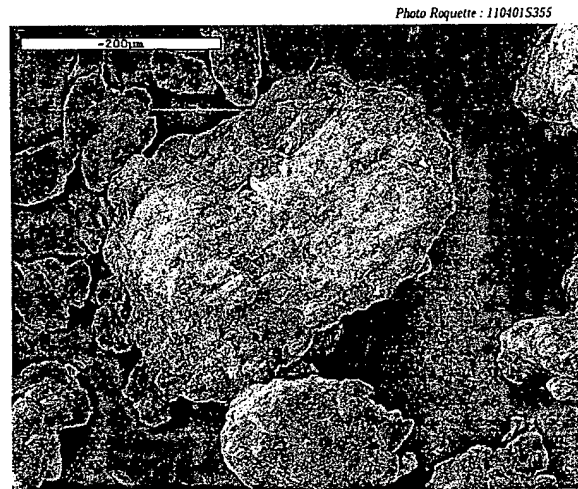


Photo 2: Lab 2695 sample X201  
Magnification: 154 X

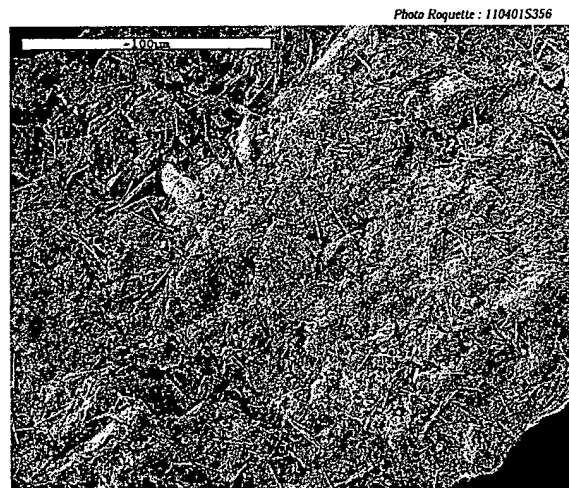


Photo 3: Lab 2695 sample X201  
Magnification: 385 X



In re application of LABERGERIE ET AL - Serial No. 09/819,496  
July 18, 2002

RECEIVED  
JUL 29 2002  
TECH CENTER 1600/2900

## ANNEX V

### ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF SERPELLONI - PEARLITOL ® SD 100 - REF LAB 2515

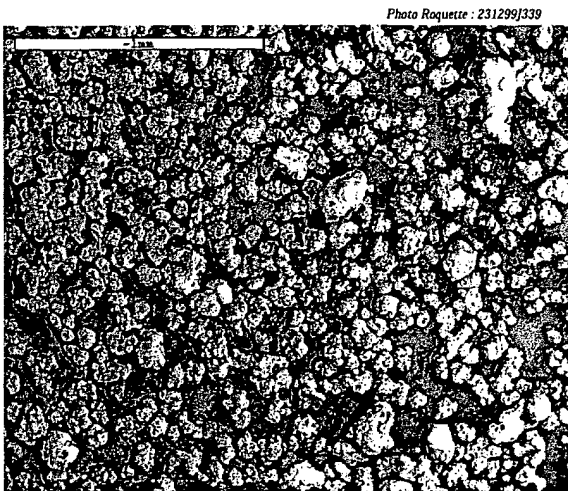


Photo 1: Pearlitol ® SD100 - Lab 2515  
Magnification: 38.5 X

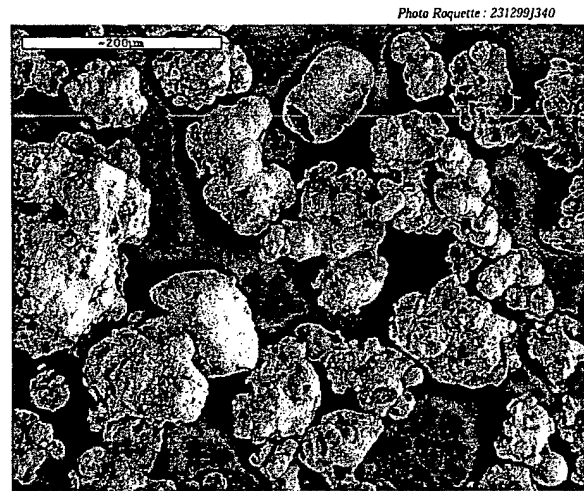


Photo 2: Pearlitol ® SD100 - Lab 2515  
Magnification: 154 X



Photo 3: Pearlitol ® SD100 - Lab 2515  
Magnification: 385 X





In re application of LABERGERIE ET AL - Serial No. 09/819,496  
July 18, 2002

RECEIVED  
JUL 29 2002  
TECH CENTER 1600/2900

## ANNEX VI

### ELECTRON MICROSCOPE PHOTOS OF THE PULVERULENT MANNITOL OF SERPELLONI - PEARLITOL ® SD 200 REF LAB E138M

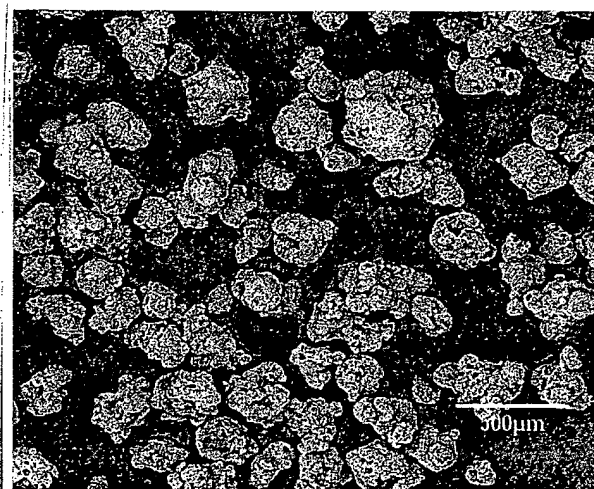


Photo 1: Pearlitol ® SD200 - Sample E138M  
Magnification: 35 X

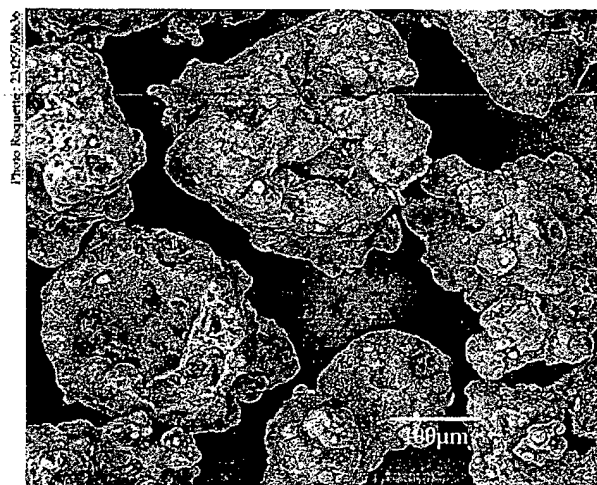


Photo 2: Pearlitol ® SD200 - Sample E138M  
Magnification: 146 X

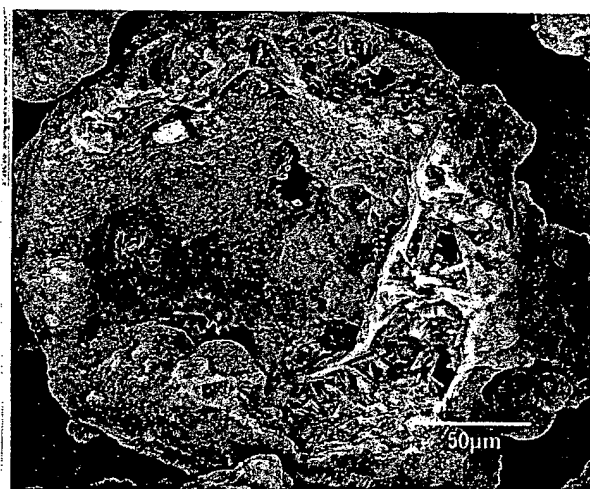


Photo 3: Pearlitol ® SD200 - Sample E138M  
Magnification: 365 X